DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

Boston Scientific Corporation
c/o Mr. Joseph Ostendorf
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K062387
Small Peripheral Cutting Balloon Monorail Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: PNO
Dated: September 25, 2006
Received: September 26, 2006

Dear Mr. Ostendorf:

This letter corrects our substantially equivalent letter of October 5, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number: K062387

Device Name: small Peripheral Cutting Balloon with Monorail Delivery System

Indications for Use:

The Small Peripheral Cutting Balloon catheters are indicated for percutaneous transluminal angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

Prescription Use X AND/OR Over-the-Counter Use _____
(part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochman
(Division Sign-Off)
Division of Cardiovascular Devices

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5. 510(k) Summary

OCT - 5 2006

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
Contact Name and Information	Angie Byland Regulatory Affairs Manager Phone: (763) 494-2887 Fax: (763) 494-2981		
Date Prepared	August 14, 2006		
Proprietary Name(s)	Small Peripheral Cutting Balloon™		
Common Name	PTA Catheter		
Product Code	LIT		
Classification of Device	Class II, 21 CFR Part 870.1250		
Predicate Device	Small Peripheral Cutting Balloon™ with Monorail Delivery System	K052038	August 16, 2005
Device Description	The small Peripheral Cutting Balloon Catheter (PCB) with Monorail (MR) delivery system has features of a conventional angioplasty catheter with advanced microsurgical capabilities. The sPCB features a balloon with 3 or 4 atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The device is inserted over a guidewire and delivered to the target lesion. When the PCB device is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. Percutaneous Angioplasty (PTA) with the PCB device allows dilatation of the target lesion with less pressure, minimizing barotrauma.		
Intended Use of Device	The small Peripheral Cutting Balloon catheters are indicated for percutaneous transluminal angioplasty of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.		
Support of Substantial Equivalence	The small Peripheral Cutting Balloon Catheter with Monorail delivery system with the modified port weld is the same indication, design, composition, and function as the Peripheral Cutting Balloon Catheter, small Monorail (K052038), cleared August 16, 2005.		

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Conclusion	Based on the indications for use and the technological characteristics, the small Peripheral Cutting Balloon with Monorail delivery system has been shown to be equivalent in intended use and is considered to be substantially equivalent to the Small Peripheral Cutting Balloon™ with Monorail delivery system (K052038, cleared June 22, 2005).